JUL - 5 2000

K001758

510(k) SUBMISSION

Summary:

Dade® Liquid™ Moni-Trol® Human is substantially equivalent to Medical Analysis Systems, Inc. ChemTRAK® Platinum Comprehensive Liquid Assayed Chemistry Control already in commercial distribution.

Medical Analysis Systems **Dade® Liquid™ Moni-Trol® Human is** a ready-to-use liquid stable assayed controls derived from a human serum matrix suitable for use in the clinical laboratory as a consistent test sample of known concentration for monitoring assay conditions in any of the listed constituents. The controls are prepared from human serum with constituents of non-human origin and purified biochemicals. Preservatives and stabilizers are added to maintain product integrity. The liquid matrix eliminates causes of vial to vial variability and, when handled as directed, provides consistency in day-to-day testing. This product will be sold in separate kits of Level 1, a "mid" level, Level 2, and as a sample pack containing all three levels (1, mid, and 2).

The controls are stable for 24 months from the date of manufacture when stored at -20°C or below. Unopened vials are stable for 60 days when stored at 2-8°C. Opened vials are stable for 7 days when stored at 2 to 8°C.

a. **Product Code:** 91JJY Multi-analyte Controls, all kinds

Proprietary Name: Dade®Tru-Liquid™ Moni-Trol® Chemistry Control Levels 1, mid, 2, and S (assayed)

Classification Name: 91 JJY Multi-analyte Controls, all kinds

Manufactured by: Medical Analysis Systems, Inc.
5300 Adolfo Road
Camarillo, CA 93012

	CFR Section:	862.1660 Quality Control Material
	Distributed by:	Allegiance Healthcare 1500 Waukeegan Road WM Building McGaw Park, IL 60085 USA Various other distributors per future negotiations.
b.	**Establishment Registration Number:**	2050068
c.	**Class:**	Based upon classification criteria in section 513(a), these controls have been classified into Class I.
	Classification Panel:	Clinical Chemistry Test Systems
d.	**Compliance with Section 514:**	These products have been classified into Class I. General Controls apply.
e.	**Proposed Labeling:**	Proposed labels and labeling, in draft form, are attached.
f.	**Triage Review:**	Tier I

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL - 5 2000

Mr. Scot D. Kinghorn
Management Representative
Vice President, Quality and Regulatory Affairs
Medical Analysis Systems, Inc.
5300 Adolfo Road
Camarillo, California 93012

Re: K001758
Trade Name: Dade® Liquid™ Moni-Trol® Human comprehensive General Chemistry Control
Regulatory Class: I
Product Code: JJY
Dated: June 8, 2000
Received: June 9, 2000

Dear Mr. Kinghorn:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Notification ● 8 June, 2000
Dade® Liquid™ Moni-Trol® Human
Comprehensive General Chemistry Control Levels 1, mid, and 2

Statement of Indications for Use

Dade® Liquid™ Moni-Trol® Human Comprehensive General Chemistry Control Levels 1, mid, and 2 is intended for use as a consistent test sample of known concentration for monitoring assay conditions in many clinical laboratory determinations. Include **Moni-Trol® Human** with patient serum specimens when assaying for any of the listed constituents. The user can compare recovered values over an extended period of time as a means of evaluating analytical precision, as well as reagent and instrument performance.

Susan Cooper 7/3/00
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K001758